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Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

TERRY PAULSEN, an individual,

Plaintiff,

vs.

ABBOTT LABORATORIES, an Illinois corporation, TAKEDA PHARMACEUTICALS OF NORTH AMERICA, INC., a wholly owned subsidiary of TAKEDA CHEMICAL INDUSTRIES LTD., an Illinois corporation, TAKEDA CHEMICAL INDUSTRIES, INC., an Illinois corporation, and TAP PHARMACEUTICAL PRODUCTS, INC., a New York corporation,

Defendants.

Case No.: 1:15-cv-04144

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Refiled Complaint
[Previous Filing Case No. 1:11-cv-04860]

Plaintiff, by and through her attorneys, ALAN S. LEVIN, M.D., J.D. and TESFAYE W. TSADIK, ESQ., on behalf of herself, upon information and belief, at all times hereinafter mentioned, allege as follows:

JURISDICTION, VENUE & TIMELINESS

1. This Court has jurisdiction pursuant to 28 United States Code § 1332, based upon diversity jurisdiction in that the Plaintiff is citizen of State that are different from the States where Defendants are incorporated and have their principal places of business. The amount in controversy exceeds seventy-five thousand dollars ($75,000.00) as to each Plaintiff.

2. This action is timely. This is a refiling of the previous case which was voluntarily dismissed without prejudice on May 29, 2014. The previous case number was 1:11-cv-04860. Section 5/13-217 of the Illinois Code of Civil Procedure provides that, if an action is voluntarily dismissed, the plaintiff may refile the lawsuit within one year or within the remaining period of limitation, whichever is greater. 735 ILCS 5/13-217.

PLAINTIFF

3. The Plaintiff, TERRY PAULSEN (hereafter "PAULSEN"), is an individual and at all times relevant hereto was a resident of the State of Georgia. PAULSEN was injected with Lupron on two occasions.

DEFENDANTS

4. The Defendant Abbott Laboratories ("Abbott") is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois.

5. The Defendant Takeda Pharmaceuticals of North America, Inc. ("TPNA") is a wholly owned subsidiary of Takeda Chemical Industries, Ltd. ("Takeda"), with its headquarters located in One Takeda Parkway, in Deerfield, Illinois 60015. TPNA's clinical development activities are conducted via Takeda Global Research & Development Center, Inc. TPNA focuses on a variety of therapeutic areas including diabetes, cardiovascular disease, central nervous system disorders, gastroenterology, bone and joint disorders, chronic kidney disease,

gynecological disorders, and infectious disease; including the development of depot leuprolide acetate, known as Lupron Depot® (hereinafter referred to as "Lupron").

6. Defendant TAP Pharmaceutical Products, Inc. ("TAP") is a joint venture between Takeda and Abbott, by and through which, acting in concert, each owns and controls a fifty percent (50%) stake in TAP. Takeda's interest in TAP is held through a subsidiary company of Takeda called Takeda America Holdings, Inc. ("Takeda Holdings"), which maintains an office at 767 Third Avenue, New York, New York 10017.

7. By agreement, Abbott, Takeda, TAP, and a TAP subsidiary, Takeda Pharmaceuticals, Inc., jointly develop and market pharmaceutical products for the American and Canadian markets. Upon information and belief, TAP is directed and controlled by Abbott and Takeda, and TAP focuses its marketing efforts on securing Lupron use and sales by physicians; including physicians within the states of New York, Georgia, and California.

FACTUAL BACKGROUND

8. TAP, along with the companies responsible for its actions (i.e. Defendants Abbott and TPNA) and their related entities, jointly, severally, acting in concert, with or through others, and the companies they own, control, or for whose actions they are responsible, has at all relevant times, been involved in and/or responsible for the research, development, testing, manufacturing and sales, distribution and/or marketing of the drug known as Lupron, directly or indirectly through an agent, affiliate or subsidiary of TAP Products or Defendants.

9. References herein to the knowledge, actions and/or omissions of the "Defendant", "Defendants" or "TAP" specifically include Abbott and TPNA, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible.

10. Lupron was developed in or around 1985, and was first approved by the United States Food and Drug Administration ("FDA") for the palliative treatment of prostate cancer on January 26, 1989.

11. Lupron was approved by the FDA as a treatment for endometriosis on or about October 22, 1990, and as a treatment for anemia associated with uterine fibroids on or about March 30, 1995.

12. In April 1998, TAP submitted a report to the FDA in which researchers disclosed that they were "concerned" because more than one-third of the women they studied who took Lupron did not "demonstrate either partial reversibility" or "a trend toward return" of bone mass in the six months after they stopped taking the drug.

13. Upon information and belief, as early as October 22, 1990, and for more than decade, TAP was aware of the continued bone loss incurred by users of Lupron, but took no corrective action, gave no adequate warning, and did not take the drug off the market.

14. In 2001, the FDA approved Lupron "add-back therapy", designed to counteract the harmful bone-depleting effects of Lupron, which involves the use of a progestin-based hormone replacement known as norethindrone.

15. Defendants knew, or should have known, based upon the state of knowledge that existed at the time regarding Lupron, and on generally accepted medical and research standards and principles, that serious long-term health problems are associated with the use of Lupron, including, but not limited to, an increased risk of significant bone mineral density loss, early development of osteoporosis, and osteopenia; neurological, ophthalmologic, pituitary, and metabolic complications; and muscle pain, joint pain, and debilitating fatigue. Defendants failed to adequately apprise Plaintiff or Plaintiff's physicians of such problems and risks, as well as a litany of other side effects.

16. The prescribing information provided to physicians and pharmacists and the patient information pamphlet did not adequately warn of these risks.

17. Defendants made certain affirmative claims which were distributed and circulated to the medical profession, and to the general public, through advertising, literature, promotional documents, brochures and other materials, which represented Lupron to be a safe and efficacious drug treatment for women with certain gynecological problems such as endometriosis and uterine fibroids.

18. Upon information and belief, Defendants misrepresented and concealed the risks inherent in the use of Lupron in their applications for FDA approval, and in representations to other governmental employees and/or agencies.

19. Plaintiff PAULSEN was injected with Lupron on two occasions beginning on or about February 2004 and ending on or about March 2004. Upon information and belief, Lupron was prescribed to treat endometriosis.

20. Plaintiff PAULSEN was treated for joint pain and was subsequently diagnosed with severe joint arthropathy in April of 2008. She was later diagnosed with osteoporosis in May of 2010, in addition to suffering from chronic joint pain, muscle pain, fatigue, and other severe and permanent injuries.

21. Plaintiff had no knowledge of her claims alleged herein, or facts sufficient to place her on inquiry notice of the claims set forth herein within two years of the filing of the previous complaint. Plaintiff did not discover, and could not have discovered through the exercise of reasonable diligence the causal connection between her injures and the negligent conduct of defendants herein.

FIRST CAUSE OF ACTION vs. ALL DEFENDANTS
(Negligence)

22. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in paragraphs "1" through "21" inclusive, as if expressly rewritten herein.

23. The negligence of the Defendants, jointly, severally, acting in concert and that of their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Negligence in formulating, analyzing, designing, fabricating, manufacturing, supplying, distributing, merchandizing, advertising, promoting, packaging, marketing, selling, and recommending Lupron in a defective condition when they knew or should have known of said defects;

b. Failing to identify, eliminate, and/or reduce the risks and hazards associated with the intended and foreseeable uses of the drug;

c. Formulating, analyzing, designing, fabricating, manufacturing, supplying, distributing, merchandizing, advertising, promoting, packaging, marketing, selling, and recommending the drug, which was unreasonably dangerous, unsafe, and defective with regard to its intended and foreseeable purposes, including off- label uses; and which lacked adequate and necessary warnings;

d. Failing to adequately test Lupron before securing FDA approval;

e. Failing to advise Plaintiffs and their physicians of the dangers associated with the use of Lupron;

f. Misrepresenting the dangers associated with the use of the drug, which deprived Plaintiffs of the opportunity to make an informed choice regarding the risks and benefits associated with said drug;

g. Failing to conduct adequate post-market surveillance of the drug; and

h. Failing to appropriately respond to adverse event reports concerning Lupron, including but not limited to notification of physicians who prescribe the drug and individuals who ingested the drug.

24. As a direct and proximate result of the aforementioned negligence of Defendants, jointly, severally, acting in concert, with or through others, and the companies they own, control, or for whose actions they are responsible, Plaintiff was caused to sustain severe and grievous injuries, including but not limited to negative effects on bone mineral density ("BMD"), osteoporosis, and/or osteopenia; ophthalmologic complications, including but not limited to diplopia and loss of vision; adverse neurological reactions; adverse pituitary reactions; and/or adverse metabolic reactions.

25. By reason of the foregoing, Plaintiff has been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000.00) in punitive damages.

SECOND CAUSE OF ACTION vs. ALL DEFENDANTS
(Strict Products Liability)

26. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs "1" through "25" inclusive, as if expressly rewritten herein.

27. At all times herein mentioned, the Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, manufactured, compounded, tested, distributed, recommended, marketed, merchandized, advertised, promoted, sold, purchased, prescribed, and administered Lupron; and the Plaintiffs used, took, or received administrations of Lupron.

28. Lupron was expected to and did, in fact, reach consumers without substantial change in the condition in which Lupron was produced, manufactured, sold, distributed, and marketed by the Defendants.

29. At all times herein described, Lupron was in an unsafe, defective, and inherently dangerous condition, and was hazardous to users, and specifically to the Plaintiffs, in the condition in which the Lupron was produced, manufactured, sold, distributed, and marketed by the Defendants.

30. At all times herein mentioned, the Defendants knew or had reason to know that Lupron was defective and unsafe.

31. At the time Plaintiff was injected with Lupron, the drug was being used for the purposes and in a manner normally intended by Defendants.

32. The Plaintiff, through her own reasonable care, could not have discovered the defects herein mentioned or perceived their danger any sooner than they did discover such defects. Defendants did intentionally and/or negligently fail to warn the Plaintiffs and others of the dangers associated with the use of Lupron.

33. Defendants were aware of and did not take reasonable steps to prevent off-label use of this medication.

34. As a direct and proximate result of the defective and unsafe condition of Lupron, Plaintiff was caused to sustain severe and grievous personal injuries, as described herein, including but not limited to negative effects on bone mineral density ("BMD"), osteoporosis, and/or osteopenia; ophthalmologic complications, including but not limited to diplopia and loss of vision; adverse neurological reactions; adverse pituitary reactions; and/or adverse metabolic reactions.

35. By reason of the foregoing, Plaintiff has been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000.00) in punitive damages.

THIRD CAUSE OF ACTION vs. ALL DEFENDANTS
(Strict Products Liability – Failure to Warn)

36. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs "1" through "35", inclusive, as if expressly rewritten herein.

37. Defendants jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, manufactured and/or supplied Lupron, and placed Lupron into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product.

38. The Lupron manufactured and/or supplied by Defendants was not accompanied by proper warnings to physicians, the medical community, or to women, regarding all possible side effects, health concerns and risks associated with the use of Lupron. The warnings and information which were given to the medical community and women consumers did not accurately reflect the symptoms, duration, scope or severity of the potential side effects, health concerns, and risks of Lupron.

39. Defendants failed to perform testing which would have shown Lupron's potential to cause serious side effects, health concerns and/or risks.

40. Defendants also failed to engage in adequate post-market surveillance and to issue appropriate post-marketing warnings and/or instructions regarding the potential side effects, health concerns, and/or risks associated with Lupron, of which Defendants were or should have

been aware. To the contrary, Defendants continued to promote Lupron aggressively without these warnings and/or instructions.

41. Had adequate warnings or instructions been provided, the Plaintiffs would not have used, taken, or received administrations of Lupron, and would not have suffered the harmful side effects, other injuries and damages described herein.

42. As a direct and proximate cause of the defective condition of Lupron which Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, designed, developed, manufactured, produced, tested, sold, marketed, supplied and/or distributed, and the absence of adequate and timely warnings about the potential risks of the drug, Plaintiff suffered those injuries and damages as described herein, including but not limited to negative effects on bone mineral density ("BMD"), osteoporosis, and/or osteopenia; ophthalmologic complications, including but not limited to diplopia and loss of vision; adverse neurological reactions; adverse pituitary reactions; and/or adverse metabolic reactions.

43. By reason of the foregoing, Plaintiff had been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000.00) in punitive damages.

FOURTH CAUSE OF ACTION vs. ALL DEFENDANTS
(Breach of Express Warranty)

44. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs "1" through "43" inclusive, as if expressly rewritten herein.

45. The Defendants expressly represented to the medical community and Lupron users that Lupron had been or was adequately tested for its intended use, that it was safe and fit for its intended purposes, and that it was of merchantable quality.

46. Members of the medical community relied upon the express representations and warranties of Defendants for use in prescribing, recommending, and/or dispensing Lupron.

47. Users of Lupron, including the Plaintiffs, relied on the express representations and warranties of the Defendants that Lupron was safe and fit for use and that it would alleviate and/or eliminate the incidence of, and symptoms associated with, endometriosis and uterine fibroids.

48. Defendants knew or should have known that said representations and warranties were in fact false and misleading, and untrue in that Lupron was not reasonably safe and fit for its intended use, and was not of merchantable quality. Defendants knew or should have known that Lupron causes or contributes to serious adverse health effects, risks, complications, and other injuries for its users as previously described herein. Consequently, Defendants breached their aforementioned express warranties.

49. As a direct and proximate result of such breach of express warranties by Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, the Plaintiff suffered and sustained permanent, severe and grievous personal injuries, including but not limited to significant loss of bone mineral density, early development of osteoporosis, chronic pain, pituitary abnormalities, neurological complications, chronic pain, debilitating pain, fatigue, spasms, and seizures.

50. By reason of the foregoing, Plaintiff has been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000.00) in punitive damages.

FIFTH CAUSE OF ACTION vs. ALL DEENDANTS
(Breach of Implied Warranty)

51. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs "1" through "50", inclusive, as if expressly rewritten herein.

52. At all times herein mentioned, Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, created, designed, formulated, fabricated, analyzed, tested, manufactured, produced, packaged, promoted, recommended, marketed, merchandized, advertised, distributed and sold Lupron.

53. The Lupron which Defendants inserted into the stream of commerce was defective, unsafe, and in an inherently dangerous condition, where it was expected to and in fact did reach users, distributors, and other persons, including the Plaintiffs, without substantial change in the condition in which it was manufactured, produced, distributed and sold.

54. Defendants impliedly represented and warranted to Lupron users and the medical community that Lupron was safe, of merchantable quality, and fit for the purpose for which said product was used.

55. Defendants impliedly represented and warranted to the users of Lupron and the medical community that Lupron was reasonably safe and fit for its intended use, and that Lupron was of merchantable quality. Defendants knew or should have known that these representations and warranties were false, misleading, and inaccurate in that Lupron was unsafe and unfit for its intended use, was not of merchantable quality, had not been appropriately and sufficiently tested, and was otherwise defective and inherently dangerous. Consequently, Defendants breached their implied warranties.

56. As a direct and proximate result of the aforementioned breach of implied warranties by Defendants, the Plaintiff suffered and sustained permanent, severe, and grievous personal injuries as set forth herein, including but not limited to negative effects on bone mineral density ("BMD"), osteoporosis, and/or osteopenia; ophthalmologic complications, including but not limited to diplopia and loss of vision; adverse neurological reactions; adverse pituitary reactions; and/or adverse metabolic reactions.

57. By reason of the foregoing, Plaintiff has been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000.00) in punitive damages.

SIXTH CAUSE OF ACTION vs. ALL DEFENDANTS
(Fraudulent Misrepresentation)

58. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs "1" through "57", inclusive, as if expressly rewritten herein.

59. At all relevant times, the Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, made false and fraudulent misrepresentations to the medical community and to users of Lupron through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, and notice letters, beginning in the 1990's and continuing into the 2000's.

60. These misrepresentations include, but are not limited to, assurances that Lupron had been tested and found to be a safe and effective treatment for, among other things, eliminating the incidence and symptoms of endometriosis and uterine fibroids.

61. Defendants knew or should have known these misrepresentations to be false. Defendants knew, or should have known, that serious long-term health problems are associated

with the use of Lupron, including, but not limited to, an increased risk of significant bone mineral density loss, early development of osteoporosis, and osteopenia; neurological, pituitary, and metabolic complications; and/or muscle and joint pain and debilitating fatigue. Defendants failed to adequately apprise Plaintiffs or Plaintiffs' physicians of such problems and risks, as well as a litany of other side effects.

62. Nevertheless, Defendants willfully, wantonly and recklessly disregarded the falsity of their statements and omissions; made these representations fraudulently and deceitfully, with the intent that they be relied upon by inducing women to seek and accept Lupron as treatment for endometriosis and/or uterine fibroids and by inducing the medical community to prescribe, dispense, purchase, administer, and otherwise disseminate Lupron to women. All of Defendants' above acts and/or omissions evince a callous, reckless, willful, and depraved indifference to the life, health, safety and welfare of the drug's intended users, including the Plaintiffs herein.

63. At the time Defendants made their misrepresentations, users of Lupron, including Plaintiffs herein, could not by the exercise of their own reasonable care, discover the falsity of Defendants' misrepresentations and instead, reasonably believed them to be true.

64. Defendants sought and in fact did obtain FDA approval of Lupron in its defective form, in part based upon Defendants fraudulent misrepresentations, and Defendants inserted Lupron into the stream of commerce, which caused harmful effects to Lupron's users, including the Plaintiffs herein.

65. Defendants knew or should have known that Lupron had been insufficiently tested, lacked adequate warnings, and would lead to serious injury amongst its users, including Plaintiff, who would rely on Defendants' misrepresentations to their detriment. Defendants

thereby breached their duty to Plaintiffs, to users of Lupron, and to the medical community, including Plaintiff's physicians.

66. As a direct and proximate result of her detrimental reliance on Defendants' fraudulent conduct and misrepresentations, disseminated jointly, severally, acting in concert, with or through others, and the companies they own, control, or for whose actions they are responsible, the Plaintiff was caused to sustain permanent, severe, and grievous personal injuries, as set forth herein, including but not limited to negative effects on bone mineral density ("BMD"), osteoporosis, and/or osteopenia; ophthalmologic complications, including but not limited to diplopia and loss of vision; adverse neurological reactions; adverse pituitary reactions; and/or adverse metabolic reactions.

67. By reason of the foregoing, Plaintiff has each been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000.00) in punitive damages.

SEVENTH CAUSE OF ACTION vs ALL DEFENDANTS
(Negligent Misrepresentation)

68. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs "1" through "67" inclusive, as if expressly rewritten herein.

69. The Defendants, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, had a duty to make accurate representations to the medical community, the Plaintiff herein, and the general public. Defendants represented, among other things, that Lupron had been tested and found to be safe and effective for the use as an injectable drug for the treatment of endometriosis.

70. Defendants knew or should have known that the drug had been insufficiently and/or inappropriately tested, that it lacked adequate warnings, and/or that it created a high risk of unreasonable and dangerous side effects and health risks, including but not limited to significant loss of bone mineral density, early development of osteoporosis, chronic pain, debilitating pain, fatigue, spasms, seizures, and pituitary problems.

71. Because Defendants did not accurately disclose Lupron's serious side effects and health risks to the medical community, the Plaintiffs, and the general public, Defendants negligently misrepresented Lupron's actual, unsafe condition. The treating physicians of Plaintiffs herein detrimentally relied on Defendants' misrepresentations in treating Plaintiffs with Lupron, and Plaintiffs themselves detrimentally relied on these misrepresentations in accepting treatment with and ingesting Lupron.

72. As a direct and proximate result of their detrimental reliance on the negligent misrepresentations by Defendants, the Plaintiff was caused to sustain severe and grievous personal injuries, including but not limited to negative effects on bone mineral density ("BMD"), osteoporosis, and/or osteopenia; ophthalmologic complications, including but not limited to diplopia and loss of vision; adverse neurological reactions; adverse pituitary reactions; and/or adverse metabolic reactions.

73. By reason of the foregoing, Plaintiff has been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000) in punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff TERRY PAULSEN demands judgment against Defendants, ABBOTT LABORATORIES, TAKEDA PHARMACEUTICALS OF NORTH AMERICA, INC., a wholly owned subsidiary of TAKEDA CHEMICAL INDUSTRIES, LTD. and TAP

PHARMACEUTICAL PRODUCTS, INC. jointly, severally, on each cause of action, for damages in the amount prayed for, with interest, together with the costs and disbursements of this action, and any and all further relief this Court deems just and proper.

DATED this 11th day of May, 2015.

BY: _____

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Attorneys for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

DATED this 11th day of May, 2015.

BY: _____

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